UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/999,690	09/08/97	GUNZBURG W	GSF97-03A

HM12/1122

HAMILTON BROOK SMITH & REYNOLDS
TWO MILITIA DRIVE
LEXINGTON MA 02173-4799

EXAMINER	
CLARK, D	
ART UNIT	PAPER NUMBER
1633	11

DATE MAILED: 11/22/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
08/999,690	Gunzburg et al.
Examiner	**Group Art Unit**
Deborah Clark	1633

☒ Responsive to communication(s) filed on *Sep 22, 1999* .

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-26* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-26* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Response to Amendment

1. Applicant's amendment and response to the previous office action has been received and entered, 09/22/99, paper no. 10. Claims 1-26 are now pending.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Priority is now perfected and granted to 03/09/95.

Claim Rejections - 35 USC § 101

3. The previously made rejection under 35 USC 101 is overcome by applicant's amendment.

Claim Rejections - 35 USC § 112

4. Claims 1-15 and 20-22 stand, and newly presented claim 26 is, rejected under 35 USC 112, 1st paragraph for reasons of record.

Applicants argue that 35 USC 112, 1st paragraph requires nothing more than objective enablement and cites *Marzocchi*. First, there is "reason for doubt" as to enablement of *in vivo* use of the claimed invention. The examiner cited references which supports that the specification does not enable the claimed invention to its full scope. Secondly, *Marzocchi* specifically says that the

teaching of the specification should correspond in scope to those used in defining the subject matter to be patented (the claims). In this case, as clearly set forth previously, the disclosure of the specification merely provides sufficient teaching for use of the invention *in vitro* whereas the claims specifically encompass the use of the invention *in vivo*. Lastly, it was clearly explained why the office doubts the enablement of the full scope of the claimed invention.

Applicants argue that the specification teaches anti-tumor effects *in vivo* and anti-viral effects *in vitro* and that no rigorous or invariable correlation is required. However, in an unpredictable art, especially where the art is actually a mating of two unpredictable arts such as that disclosed herein, the teaching must be correlatable to that claimed. No "rigorous" or "invariable" correlation was required, neither was any mention made that clinical trials were needed. A therapeutic result in an art accepted animal model which reflects the actually claimed invention is sufficient. Applicants state that Bowman, Verma, and Orkin merely address clinical applications of gene therapy. However, both Orkin and Verma go much deeper than merely discussing the clinical applications, and Bowman was relied on for the teaching regarding anti-microbial peptides, not gene therapy. Applicants cite *In re Brana* and argue that clinical data is not a requirement. First, clinical data has not been required (see above). Secondly, the quote from *Brana* specifically says that the correlation is dependent upon the stat of the prior art, which is specifically what the examiner has stated and supported.

The examiner has provided evidence and reasoning as to why applicant's working examples are not correlatable to the claimed invention. Applicant's amendment is noted however

the intended use as stated in the claims themselves continues to encompass any eukaryotic cell, *in vitro* or *in vivo*. This aspect of the rejection may be overcome for claims 1-13, 20, 21, and 26 if in claim 1, line 1, and claim 9, part (a), line 1 the phrase "for introducing DNA into an eukaryotic cell, the vector" was deleted; and in claims 14 and 15 the cell population was clearly limited to cells that were isolated or in culture.

Applicants argue that the full breadth of the claims is enabled because they have provided representative examples of the claimed genus. The examiner does not agree. As explained in the previous office action the claimed genus encompasses any peptide which has an anti-microbial anti-viral, or anti-tumor effect. This would encompass antigenic epitopes of viruses, cytokines, perhaps even antisense, none of which are discussed within the specification. The specification discloses the genus, lytic peptides, not anti-microbial peptides. Further, it is not clear how a tumor fits within this class since a tumor is not actually a microbe (see below and in the previous office action).

Therefore, the claims stand or are rejected under 35 USC 112, 1st paragraph as not enabled for the full scope of the claimed invention.

5. Claims 16-19 and 23-25 stand rejected under 35 USC 112, 1st paragraph for reasons of record.

Applicants refer to the argument as addressed above, likewise the examiner refers to the discussion above. The claims are not enabled for use *in vivo*. Applicants specifically cite a statement made by Boman that says that "**in some cases** cecropin P1 **could** be useful" (emphasis

added). The Boman reference when taken in full provides clear support that the state of the art of using lytic peptides for therapy *in vivo* is unpredictable and not an established art. Further, the same cited statement continues to say that "but the dose given would be critical". Furthermore, none of the claims are limited to cecropin P1, not these "some cases" where the cecropin P1 is useful; nor could they be since we do not know when these "some cases" are, or what dose to give.

Therefore, the claims stand rejected under 35 USC 112, 1st paragraph for reasons of record.

6. Claims 1-25 stand, and newly presented claim 26 is, rejected under 35 USC 112, 2nd paragraph for reasons of record as addressed below.

Claims 1, 2, 9, 23, and 25 continue the recite the term "derivatives". Applicants have amended the claims to state that the "derivatives" are biologically active. However, because the term derivative is indefinite as explained in the previous office action. Biological activity does not add any definition to the term and the meets and bounds of the claims remain unclear. As stated previously derivative simply means "derived from". Therefore, any peptide which has been derived from the recited peptides is encompassed even if every amino acid in the sequence has been substituted or deleted. Therefore, it is impossible to define the meets and bounds of the claims.

Claims 1, 2, 9, and 23 continue to recite "anti-microbial peptide". Applicants argue that this is a term of art and that the skilled artisan is clearly apprised of the claimed invention. The

examiner does not agree. The skilled artisan would interpret the term in a much broader aspect as stated previously by the examiner. It is not clear that the skilled artisan would accept Boman's definition because even Boman uses the term as describing a class of antibiotics. The specification does not contemplate this definition of the term and the two definitions are in contrast to each other even though both the specification and Boman use lytic peptides as the example. The peptide would be taken to mean any peptide that would target a microbe by the skilled artisan.

Claims not specifically discussed above stand rejected due to their dependence upon one or more of the discussed claims.

Any reasons for the previous rejection which was not discussed above, have been overcome or withdrawn.

Claim Rejections - 35 USC § 103

7. The previously made rejection under 35 USC 103 over Cooper in view of Gunzberg is overcome because applicants have perfected the claim to priority.

8. The previously made rejection under 35 USC 103 over Cooper in view of Temin or Gilboa is withdrawn based upon applicant's assertion that one of skill in the art would not have expected success in using the claimed invention because it was well known at the time of invention that anti-microbial peptides interfered with processing of the gag-pol region of retroviruses and therefore, the combination would not have been *prima facie* obvious.

Conclusion

9. No claim is allowed.

10. The claims are free of the prior art of record for reasons stated in #8 above, and in #12 of the previous office action.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Clark whose telephone number is (703) 305-4051. The examiner can normally be reached on Mondays-Fridays from 7:10 a.m. EST to 3:40 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jasemine Chambers, can be reached on (703) 308-2035. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DRC

11/15/99

Jasemine C. Chambers

Jasemine C. Chambers
SPE
TC 1600